

## POSSIBLE CAUSES AND TREATMENT OF FLUID ULTRAFILTRATION AND PERIGRAFT SEROMA FORMATION

Perigraft seroma, alternatively referred to as “perigraft fluid accumulation” or “hygroma,” is a sterile fluid collection enclosed within the pseudomembrane that surrounds a vascular prosthesis.<sup>1,2</sup> Development of a perigraft seroma is a possible complication after various types of reconstructive vascular procedures.<sup>3,4</sup> Perigraft seromas have been most notably observed after implantation of subcutaneously tunneled grafts such as axillofemoral bypass or hemodialysis access grafts,<sup>5</sup> and can additionally occur as a complication of aortic reconstruction.<sup>6</sup> Seroma formation has been suggested to be a rare complication associated with these procedures,<sup>7</sup> although the exact prevalence of perigraft seromas is difficult to estimate due to its infrequency and possible delayed onset<sup>8</sup> and typically asymptomatic nature.<sup>3,5</sup> Within the reviewed literature, perigraft seroma rates are reported as being between 0.48% and 31%<sup>6,9-30</sup> among patients that underwent vascular reconstructive surgery. Along with infrequency and delayed onset, the wide range of reported rates of perigraft seroma could be attributed to which diagnostic technique is used. Higher rates of perigraft seromas have been reported when computed tomography (CT) diagnostic imaging is utilized<sup>5,30</sup> compared to when physical exams alone are used for diagnosis.

The precise etiology of perigraft seroma remains unknown.<sup>3,31-33</sup> At least two potential mechanisms are known to result in perigraft seroma formation around vascular prostheses: serous fluid ultrafiltration through the graft wall and serous fluid collection from traumatized tissues. Perigraft seroma formation is known to occur in all material types, graft sizes and applications used in vascular surgery.

Gore recognizes seroma as a known possible complication of vascular surgery. Warnings and precautions in the *Instructions for Use* (IFU) for Gore vascular grafts address risk reduction of potential causative factors.

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## Presentation and diagnosis

In various vascular applications, perigraft seroma may present subcutaneously as a raised, palpable, fluid mass.<sup>31</sup> In one case, a perigraft seroma presented as spontaneous exteriorization; however, the authors stated this is a rare presentation.<sup>34</sup> In other situations, especially pediatric cardiac applications, perigraft seroma may not be detected during physical examination. According to Landis et al., perigraft seroma is typically asymptomatic; however, in rare cases the seroma can expand,<sup>35</sup> become infected<sup>36</sup> and even burst.<sup>37,38</sup> If symptoms do occur, they can include sensation of fluid mass, feeling of pressure, area tenderness or limb ischemia.<sup>38</sup>

Twenty-five percent of perigraft seromas occur in the first month postoperatively,<sup>37</sup> although perigraft seroma can occur a year after the initial prosthesis implantation<sup>39</sup> and, in rare cases, up to ten years postoperatively.<sup>40</sup> According to Wolff et al.,<sup>30</sup> seroma may be an indication that the graft failed to incorporate, suggesting that even asymptomatic seromas are important to diagnose and monitor. The diagnosis of seroma can be a difficult one to make; aneurysm and infection should be ruled out before reaching a seroma diagnosis.<sup>41</sup> It is often suggested, in concurrence with published literature,<sup>42</sup> that prior to any invasive procedure a CT scan of the affected area should be performed to demonstrate the presence of the perigraft seroma and whether the graft is still intact.

## Potential etiology

The etiology of serum or plasma ultrafiltration through a vascular graft wall, or fluid collection around a prosthetic graft, is not well understood.<sup>8,43,44</sup> It has been reported that perigraft seroma is a possible complication of reconstructive vascular surgery, regardless of whether open surgery or an endovascular approach is used.<sup>45</sup> Perigraft seroma formation has additionally been exhibited across different types of grafts. Blumenberg et al.,<sup>42</sup> presents a review of 279 cases of perigraft seroma formation, and it was found that 55% of the cases were associated with knitted polyester vascular grafts, 34% with expanded polytetrafluoroethylene (ePTFE), 2.4% with autogenous vein and 1.6% with bovine heterograft.

General suggestions of perigraft seroma etiology have included the presence of a humoral fibroblast inhibitor,<sup>3,4,43</sup> “wetting” of the graft wall,<sup>42,46-50</sup> fat liquefaction,<sup>42</sup> allergic reaction to polyester vascular grafts,<sup>42</sup> creation of an oversized tissue tunnel,<sup>42</sup> immune response<sup>51</sup> and increased porosity of the graft, possibly related to graft handling during insertion.<sup>48</sup> A 41% increase in leakage through “bent” [kinked] segments of grafts has been seen, but there is no reported relation between anastomotic angle and leakage.<sup>52</sup>

### Immediate ultrafiltration

Several authors have described immediate ultrafiltration of fluid through the graft wall.

Reported possible causes of immediate ultrafiltration include:

- Premature wetting of the graft with organic solvents.<sup>42</sup>
- Excessive manipulation of the graft with blood.<sup>42</sup>
- Over-manipulation of the graft with surgical instruments.<sup>52</sup>
- Forcing irrigating solutions through the graft wall.<sup>49</sup>
- Initial blood flow through the graft.<sup>50</sup>
- Antibiotic irrigation of the graft.<sup>46</sup>
- Genetic trait of the patient.<sup>53</sup>
- Low blood viscosity and anticoagulation.<sup>47</sup>

### Postoperative ultrafiltration

Several authors have described postoperative ultrafiltration of fluid through a graft wall.<sup>42,46,49,50,52,54</sup> In 1968, perigraft seroma formation leading to plasma seepage was reported in polyester vascular grafts following degeneration of the inner fibrous capsule.<sup>55</sup> Other possible causes of postoperative ultrafiltration include localized increase in blood velocity,<sup>52</sup> and lack of tissue attachment to the graft in the “weeping” area.<sup>52</sup> It has been suggested recently that subclinical infections of vascular grafts caused by “slime-producing” *Staphylococcus epidermidis* may lead to postoperative fluid ultrafiltration through dissolution of graft wall biologic and cellular contents.<sup>56</sup>

### Graft Wetting

Graft wetting has been thought to contribute to the formation of perigraft seroma. Graft wetting is described by Dauria et al.,<sup>52</sup> as the phenomenon in

which a hydrophobic PTFE graft becomes hydrophilic after contact with blood or another fluid. It is thought that leaking of serum or blood can be caused by lack of or altered surface tension of a PTFE graft.<sup>46</sup> These events are normal and occur fairly slowly after exposure of the graft wall to blood. As these fluids simultaneously penetrate, the interstitial air within the graft wall is replaced. When all the air has been displaced by fluids, the graft is said to have become “wetted” by fluid and changes in appearance from white to transparent, appearing like a natural vessel. Typically, coagulum has formed in the graft wall and fluid ultrafiltration does not occur. Abnormal clotting factors or anticoagulant therapy may impede coagulum formation in the graft wall, and weeping of plasma, serum or sero-sanguinous fluid may occur. It is stated within the literature that in order to reduce risk of perigraft seromas, graft wetting should be avoided.<sup>52</sup>

## Evaluation of Gore graft devices

To help prevent occurrence of ultrafiltration or perigraft seromas, every GORE-TEX® Vascular Graft must pass a water entry pressure (WEP) test prior to being released for sale. The test is designed to ensure a vascular graft will resist water passage at pressures up to 181 mmHg. Any graft that does not pass the WEP test is rejected. W. L. Gore & Associates has examined the microstructure of retrieved and explanted vascular grafts involved in serum or plasma ultrafiltration through the graft wall. No correlation was found between microstructure and ultrafiltration. Regarding GORE-TEX® Stretch Vascular Grafts versus non-stretch vascular grafts, we have not seen an increase in fluid leakage or seroma with our stretch grafts. In addition, physicians should consider the IFU warnings and precautions in order to reduce the risk of seroma formation.

## Treatment and management

Gore does not recommend any specific method of treatment and management and defers to the physician’s medical judgment. The literature indicates that intraoperative serous ultrafiltration through the graft wall may be successfully treated by replacing the graft material at the ultrafiltrating site,<sup>42</sup> using fibrin glue and topical thrombin to “preclot” the graft in situ,<sup>50</sup> wrapping the graft in

collagen fleece soaked with fibrin glue,<sup>54</sup> replacing the entire graft with the same or different type of graft material<sup>52</sup> or waiting for the ultrafiltration to cease.<sup>46,49</sup>

Additionally, postoperative seroma has been reportedly treated surgically by replacing the graft material at the ultrafiltrating site, replacing the graft with the same or another type of graft,<sup>3,38,42,52,57,58</sup> aspiration of the serum or plasma,<sup>3,4,31,42,59</sup> drainage of the perigraft fluid,<sup>48,60,61</sup> pseudocapsule resection,<sup>31,42</sup> obliterating the space around a graft with microfibrillar collagen<sup>3,32,54</sup> or using fibrin glue and topical thrombin to “preclot” the graft in situ.<sup>50</sup> Along with open surgery, endovascular techniques, such as endovascular relining of the graft, have been described as a feasible treatment option for perigraft seroma.<sup>62,63</sup> However, Reyes Valdivia et al.,<sup>38</sup> states that open surgical treatment should remain the gold standard, as endovascular treatments are in need of more clinical evidence.

Non-surgical management of perigraft seroma described within the literature included plasmapheresis treatments<sup>43</sup> and monitoring the patient closely over time.<sup>31,41,42,48</sup> Not all seromas necessitate intervention; i.e., Buche et al.,<sup>48</sup> states that “watchful waiting” of seromas is their recommendation, as secondary infection can pose risk.

In conclusion, it is likely that biochemical, mechanical and structural issues act synergistically in the formation of seromas.<sup>52</sup> Any adverse event involving Gore vascular grafts should be reported to W. L. Gore & Associates and the country specific regulatory authorities immediately.

## Product labeling

Gore recognizes seroma as a known possible complication of vascular surgery. The IFU contains warnings, precautions and instructions to reduce the risk of ultrafiltration/seroma. Please ensure you are familiar with the appropriate instructions and safety information in the IFU when handling, tunneling and implanting a Gore vascular graft to mitigate this risk. Refer to the applicable IFU available at [eifu.goremedical.com](http://eifu.goremedical.com) for a complete description of all indications, directions, warnings, precautions and adverse events.

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